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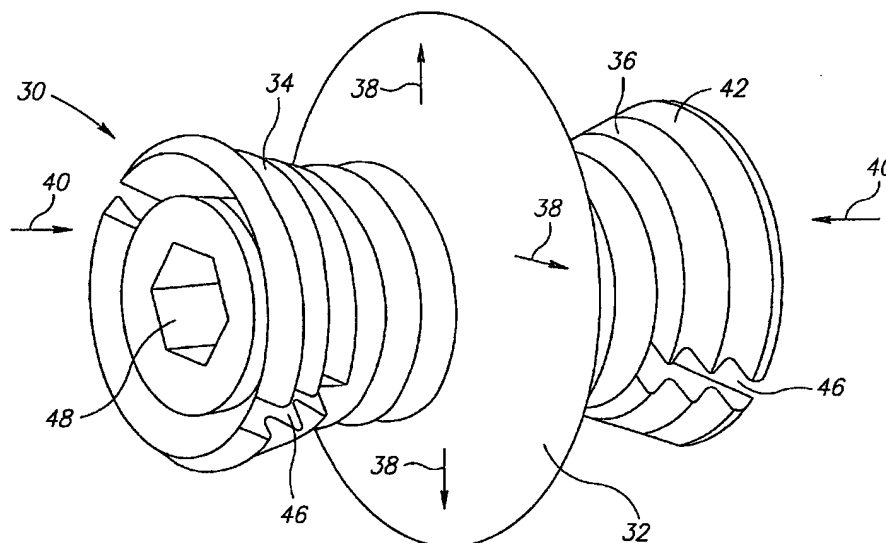
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(54) Title: FACET PROSTHESIS



(57) Abstract: An article including a facet prosthesis (30) at least partially mounted in a lumen artificially formed between superior and inferior halves of a facet joint, and an elastomeric cushioning element (32) disposed in the facet prosthesis.

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## FACET PROSTHESIS

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 USC §119 to U.S. Provisional Patent Application Serial No. 60/512,193, filed on October 20, 2003, which is incorporated herein by reference.

## FIELD OF THE INVENTION

The present invention relates to human prostheses, and more particularly to prostheses for a spinal facet joint.

## BACKGROUND OF THE INVENTION

Traumatic, inflammatory, metabolic, synovial, neoplastic and degenerative disorders of the spine can produce debilitating pain that can have severe socioeconomic and psychological effects. One of the most common surgical interventions today is arthrodesis, or spine fusion, of one or more motion segments, with approximately 300,000 procedures performed annually in the United States. Clinical success varies considerably, depending upon technique and indications, and consideration must be given to the concomitant risks and complications. For example, it has been shown that spine fusion decreases function by limiting the range of motion for patients in flexion, extension, rotation, and lateral bending. Furthermore, it has been shown that spine fusion creates increased stresses and, therefore, accelerated degeneration of adjacent non-fused motion segments. Additionally, pseudoarthrosis, as a result of an incomplete or ineffective fusion, may reduce or even eliminate pain relief for the patient. Also, the fusion device, whether artificial or biological, may migrate out of the fusion site.

Recently, several attempts have been made to recreate the natural biomechanics of the spine by use of an artificial disc. Artificial discs provide for articulation between vertebral bodies to recreate the full range of motion allowed by the elastic properties of the natural intervertebral disc that directly connects two opposed vertebral bodies.

However, the artificial discs proposed to date do not fully address the mechanics of motion of the spinal column. In addition to the intervertebral disc, posterior elements called facet joints help to support axial, torsional, and shear loads that act on the spinal column. Furthermore, facet joints are diarthroidal joints that provide both sliding articulation and load transmission features. The effects of their absence as a result of facetectomy has been observed to produce significant decreases in the stiffness of the spinal column in all planes of motion: flexion and extension, lateral bending, and rotation.

Furthermore, contraindications for artificial discs include arthritic facet joints, absent facet joints, severe facet joint tropism or otherwise deformed facet joints.

### SUMMARY OF THE INVENTION

The present invention is directed to facet joint prostheses, as is described more in detail hereinbelow.

There is thus provided in accordance with an embodiment of the present invention an article including a facet prosthesis at least partially mounted in a lumen artificially formed between superior and inferior halves of a facet joint, and an elastomeric cushioning element disposed in the facet prosthesis.

The facet prosthesis can include one or more of the following features. For example, the elastomeric cushioning element can include first and second mechanical fasteners at opposite ends thereof, which are attachable to superior and inferior halves of the facet joint. The elastomeric cushioning element can expand radially outward upon axial movement of the first and second mechanical fasteners towards each other. The first and second mechanical fasteners can include an expandable sleeve member in which is disposed a wedge, wherein insertion of the wedge into the expandable sleeve member expands the expandable sleeve member radially outwards. The expandable sleeve member can include an axial slit formed therein. The elastomeric cushioning element can include a plurality of elastomeric balls disposed in the lumen and sealed in the lumen with end caps. The elastomeric cushioning element can include a wire coil coated with an elastomeric material disposed in the lumen and sealed in the lumen with end caps. The wire coil can be constructed of a shape memory alloy.

### BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

Figs. 1A and 1B are pictorial illustrations of part of a human spine including a facet joint;

Figs. 2A and 2B are pictorial illustrations of a facet prosthesis in an uncompressed and compressed from, respectively;

Fig. 3 is a pictorial illustration of lumens being formed through aligned superior and inferior processes of adjacent vertebrae;

Fig. 4 is a pictorial illustration of the facet prosthesis of Figs. 2A and 2B implanted within a facet joint between two adjacent vertebrae;

Fig. 5 is a pictorial illustration of a facet prosthesis including an elastomeric cushioning element, constructed and operative in accordance with another embodiment of the present invention;

Figs. 6A and 6B are pictorial illustrations of a facet prosthesis including an elastomeric cushioning element, constructed and operative in accordance with yet another embodiment of the present invention, respectively showing the prosthesis installed in a facet joint and showing a wire coil coated with an elastomeric material that forms part of the prosthesis; and

Figs. 7A and 7B are pictorial illustrations of a facet prosthesis including an elastomeric cushioning element, constructed and operative in accordance with still another embodiment of the present invention, respectively showing the prosthesis installed in a facet joint and showing a wire coil coated with an elastomeric material that forms part of the prosthesis.

#### DESCRIPTION OF EMBODIMENTS

Reference is now made to Figs. 1A and 1B, which illustrate a structure of a human spine, in particular the lumbar vertebrae including a facet joint.

Figs. 1A and 1B illustrate the fourth and fifth lumbar vertebrae L4 and L5, respectively, in a lateral view (while in anatomic association) and in a superior view (separately). The lumbar vertebrae (of which there are a total of five) are in the lower back, also called the "small of the back."

As is typical with vertebrae, the vertebrae L4 and L5 are separated by an intervertebral disk 25. The configuration of the vertebrae L4 and L5 differ somewhat, but each (like vertebrae in general) includes a vertebral body 10, which is the anterior, massive part of bone that gives strength to the vertebral column and supports body weight. The vertebral arch 12 is posterior to the vertebral body 10 and is formed by the right and left pedicles 14 and lamina 16. The pedicles 14 are short, stout processes that join the vertebral arch 12 to the vertebral body 10. The pedicles 14 project posteriorly to meet two broad flat plates of bone, called the lamina 16.

Seven other processes arise from the vertebral arch. Three processes, called the spinous process 18 and two transverse 20 processes, project from the vertebral arch 12 and afford attachments for back muscles, forming levers that help the muscles move the vertebrae. The remaining four processes, called articular processes, project superiorly from the vertebral arch (and are thus called the superior articular processes 22) and inferiorly from the vertebral arch (and are thus called the inferior articular processes 24).

The superior and inferior articular processes 22 and 24 are in opposition with corresponding opposite processes of vertebrae superior and inferior adjacent to them, forming joints, called zygapophysial joints or, in short hand, the facet joints or facets. Facet joints are found between adjacent superior and inferior articular processes along the spinal column and the facet joints permit gliding movement between the vertebrae L4 and L5.

The facet joints can deteriorate or otherwise become injured or diseased, causing lack of support for the spinal column, pain, and/or difficulty in movement.

As described herein, a facet joint has a superior half and an inferior half, with cartilage therebetween. The superior half of the joint is formed by the vertebral level below the joint, and the inferior half of the joint is formed by the vertebral level above the joint. For example, in the L4-L5 facet joint, the superior half of the joint is formed by structure on the L-5 vertebra, and the inferior half of the joint is formed by structure on the L-4 vertebra.

Reference is now made to Figs. 2A and 2B, which illustrate a facet prosthesis 30, constructed and operative in accordance with an embodiment of the present invention. Facet prosthesis 30 may include an elastomeric cushioning element 32, constructed of an elastomeric material, such as but not limited to, polyurethane or polyurethane containing materials, silicone or silicone containing materials, polyethylene based elastomers, hydrogels, and polypropylene containing materials, and the like, or any combination thereof. First and second mechanical fasteners 34 and 36 may be provided at opposite ends of the cushioning element 32, which are attachable to the superior and inferior halves 22 and 24 (Figs. 1A and 1B) of the facet joint, as described hereinbelow.

The elastomeric cushioning element 32 may initially have an oblong shape (Fig. 2A) prior to implantation in the facet joint. The elastomeric cushioning element 32 may then expand radially outwards (as indicated by arrows 38 in Fig. 2B) upon axial (e.g., compressive) movement of the first and second mechanical fasteners 34 and 36 towards each other (as indicated by arrows 40 in Fig. 2B).

In one non-limiting example, first and second mechanical fasteners 34 and 36 may be constructed as an expandable sleeve member 42 in which is disposed a wedge 44. Insertion of the wedge 44 into expandable sleeve member 42 in the direction of arrow 40 expands expandable sleeve member 42 radially outwards in the direction of arrows 38. Wedges 44 may be part of a threaded fastener, which may be screwed into expandable sleeve member 42, similar to an expansion bolt (also called an anchor bolt or molly bolt)

used to anchor objects on soft walls or ceilings. The expandable sleeve member 42 may have an axial slit 46 formed therein to facilitate outward expansion thereof. Wedges 44 may have a hexagonal socket 48 for turning with an Allen key and the like. The expandable sleeve member 42 may be made of a plastic, such as but not limited to, nylon, DELRIN or polyurethane, for example, or from a metal, such as but not limited to, stainless steel. Wedge 44 may be made of metal, such as but not limited to, stainless steel, titanium alloy, cobalt chromium alloys, ceramics, or other hard, rigid materials, or may be made of a plastic, such as but not limited to, nylon, DELRIN or polyurethane.

Reference is now made to Fig. 3, which shows a side view of a facet joint prior to placement of a facet prosthesis within the joint.

When adjacent vertebra 29 are aligned, and the superior articular facet 22 of one vertebra faces the inferior articular facet 24 of an adjacent vertebra facet, two lumens, or holes, 26 and 28 may be formed, such as by drilling with a drill 30, through the aligned superior and inferior processes of the adjacent vertebrae 29.

The facet prosthesis 30 may then be inserted in the lumens 26 and 28. During insertion, the sleeve member 42 has not yet been expanded, so that the prosthesis 30 has a smaller diameter than the lumens 26 and 28 to aid in insertion of the prosthesis. Afterwards, the sleeve member 42 is expanded by the above-described action of wedges 44, thereby anchoring facet prosthesis 30 in the lumens 26 and 28 formed in the facet joint, as seen in Fig. 4. In this installed orientation, the elastomeric cushioning element 32 is in its compressed form (expanded radially outward).

Reference is now made to Fig. 5, which illustrates a facet prosthesis 50, constructed and operative in accordance with another embodiment of the present invention. In facet prosthesis 50, the elastomeric cushioning element includes a plurality of elastomeric balls 52 disposed in a lumen 54, which may be formed by drilling through cartilage between superior and inferior halves 22 and 24. Access may be gained to lumen 54 alternatively by drilling an access hole 55 directly through superior half 22. The elastomeric balls 52 may be sealed in lumen 54 with end caps 56. Elastomeric balls 52 may be constructed of an elastomeric material, such as but not limited to, polyurethane or polyurethane containing materials, silicone or silicone containing materials, polyethylene based elastomers, hydrogels, and polypropylene containing materials, and the like, or any combination thereof, and may have any suitable size. The term "balls" encompasses not only spherical shaped objects, but also oblong, ellipsoidal, prismatic and other shapes that may be placed in lumen 54.

Reference is now made to Figs. 6A and 6B, which illustrate a facet prosthesis 60, constructed and operative in accordance with yet another embodiment of the present invention. In facet prosthesis 60, the elastomeric cushioning element includes a wire coil 62 coated with an elastomeric material 64, such as but not limited to, polyurethane or polyurethane containing materials, silicone or silicone containing materials, polyethylene based elastomers, hydrogels, and polypropylene containing materials, and the like, or any combination thereof. The wire coil 62 may be constructed of a shape memory alloy, such as but not limited to, NITINOL.

The elastomeric coated wire coil 62 may be disposed in lumen 54, which may be formed by drilling through cartilage between superior and inferior halves 22 and 24. The elastomeric coated wire coil 62 may be sealed in lumen 54 with end caps 66.

Figs. 7A and 7B illustrate a facet prosthesis 70, very similar to facet prosthesis 60, except that facet prosthesis 70 may be introduced into lumen 54 through a passageway 72 formed by drilling directly through superior half 22. Both facet prostheses 60 and 70 may have any shape or size, such as but not limited to, round, square, oblong, elliptical, triangular, etc.

Although various specific implementations have been described, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, other alternatives, modifications, and variations that fall within the scope of the following claims.

## CLAIMS

What is claimed is:

1. An article comprising:  
a facet prosthesis at least partially mounted in a lumen artificially formed between superior and inferior halves of a facet joint; and  
an elastomeric cushioning element disposed in said facet prosthesis.
2. The article according to claim 1, wherein said elastomeric cushioning element includes first and second mechanical fasteners at opposite ends thereof which are attachable to superior and inferior halves of the facet joint.
3. The article according to claim 2, wherein said elastomeric cushioning element expands radially outwards upon axial movement of said first and second mechanical fasteners towards each other.
4. The article according to claim 2, wherein said first and second mechanical fasteners comprise an expandable sleeve member, the facet prosthesis further comprising a wedge insertable into said expandable sleeve member, wherein the sleeve expands radially upon insertion of the wedge into the sleeve.
5. The article according to claim 4, wherein said expandable sleeve member has an axial slit formed therein.
6. The article according to claim 1, wherein said elastomeric cushioning element includes a plurality of elastomeric balls disposed in said lumen and sealed in said lumen with end caps.
7. The article according to claim 1, wherein said elastomeric cushioning element includes a wire coil coated with an elastomeric material disposed in said lumen and sealed in said lumen with end caps.
8. The article according to claim 7, wherein said wire coil is constructed of a shape memory alloy.



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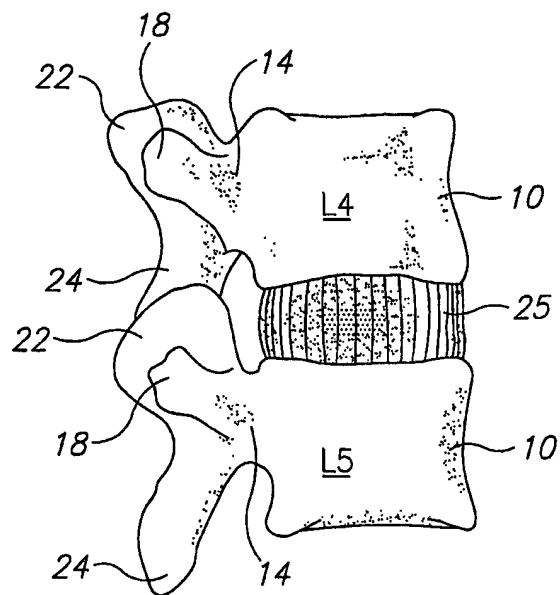


FIG. 1A

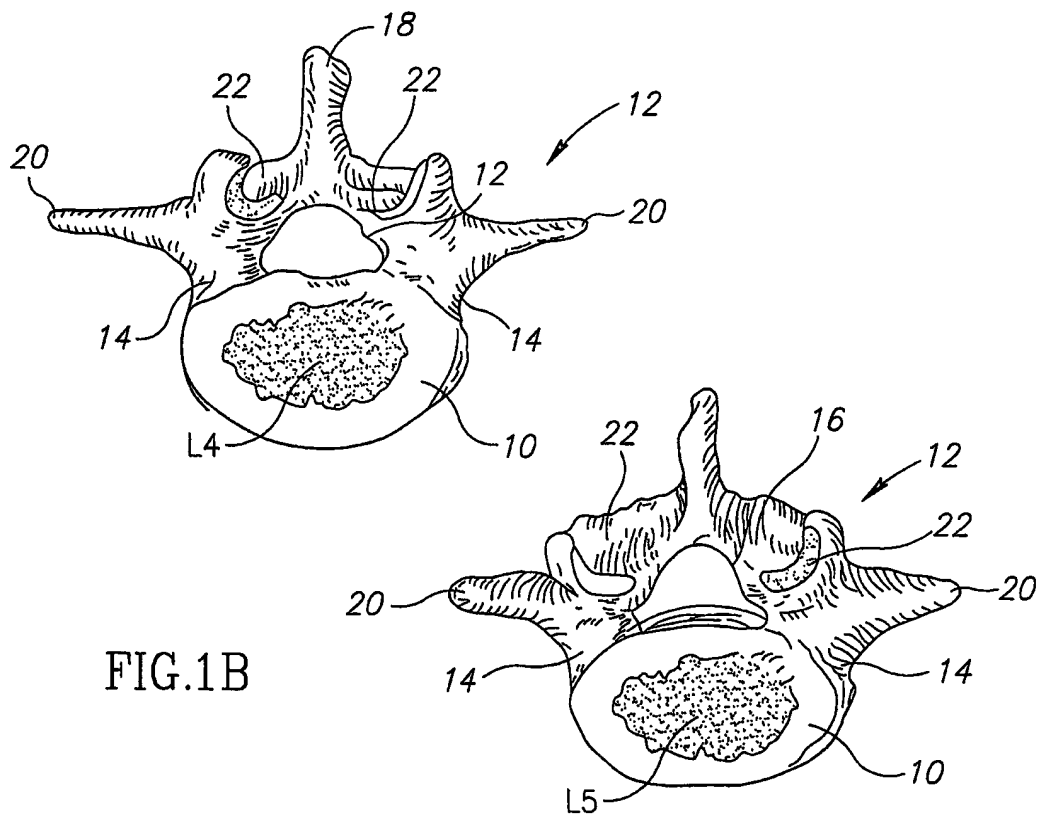


FIG. 1B

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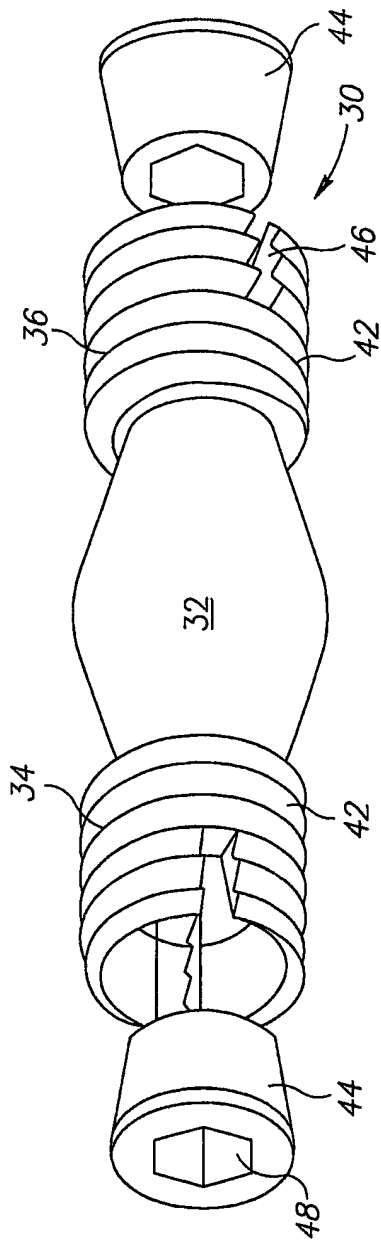


FIG. 2A

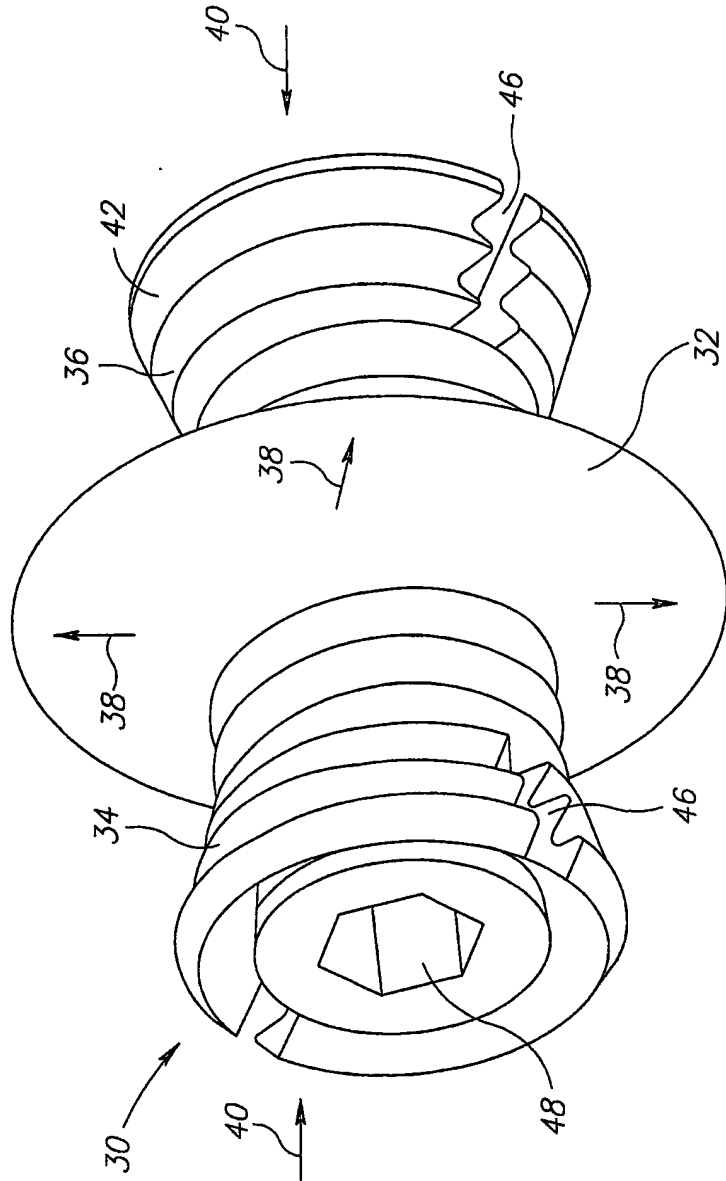


FIG. 2B

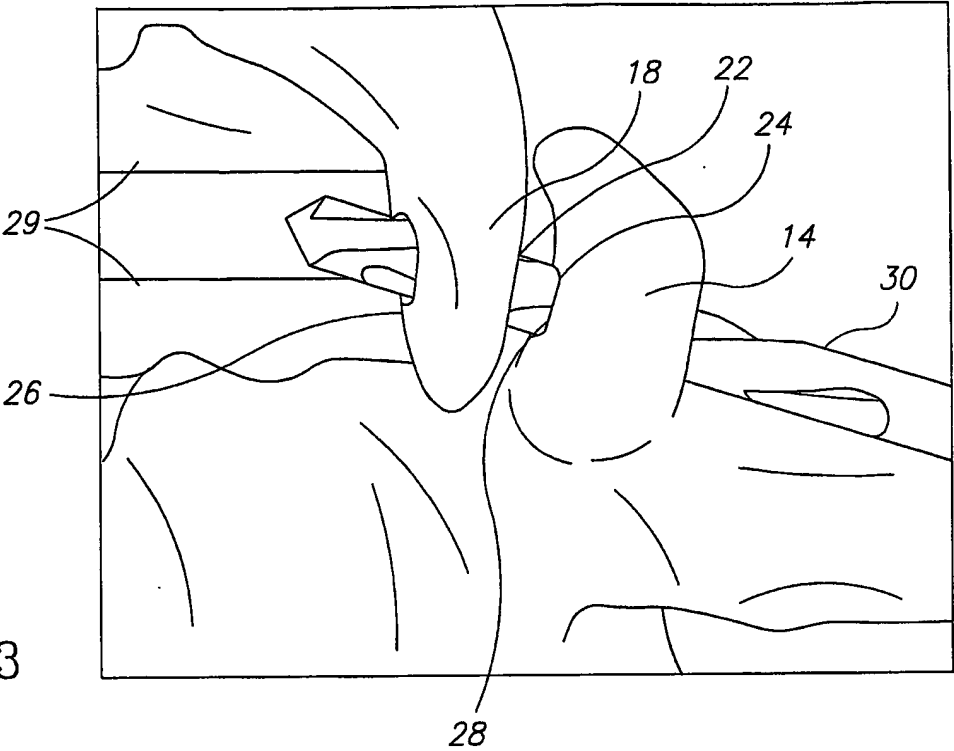


FIG. 3

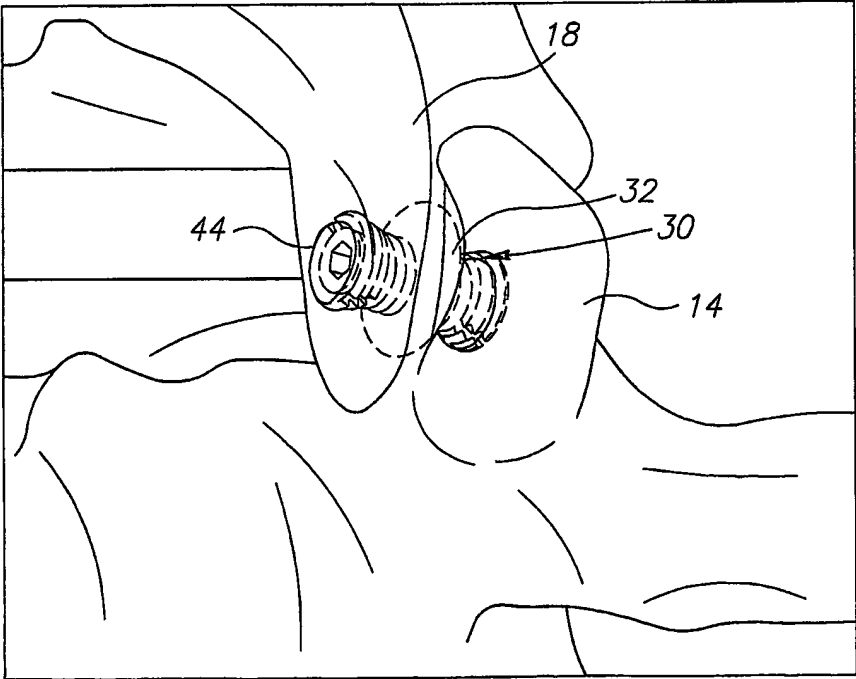


FIG. 4

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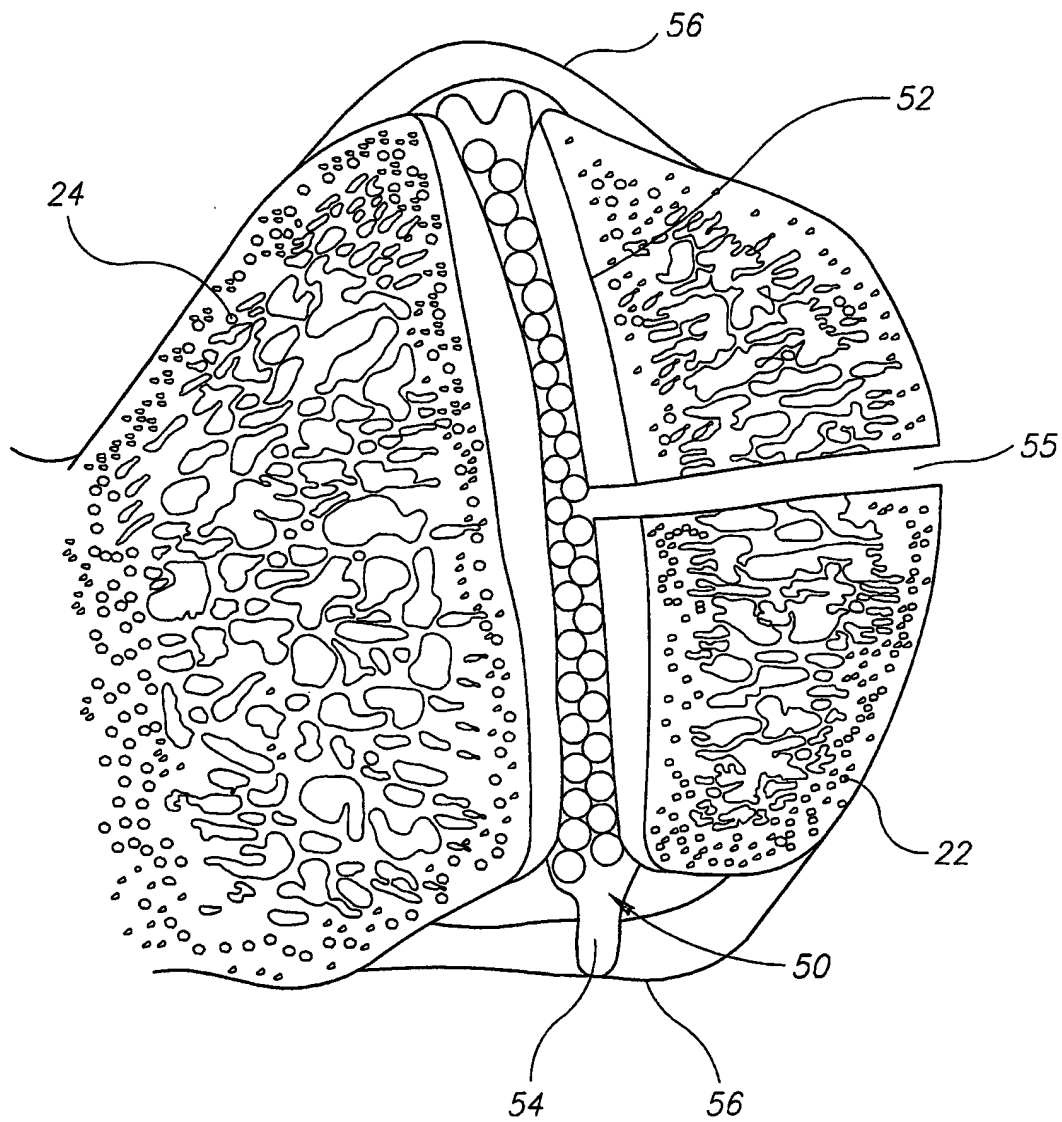


FIG. 5

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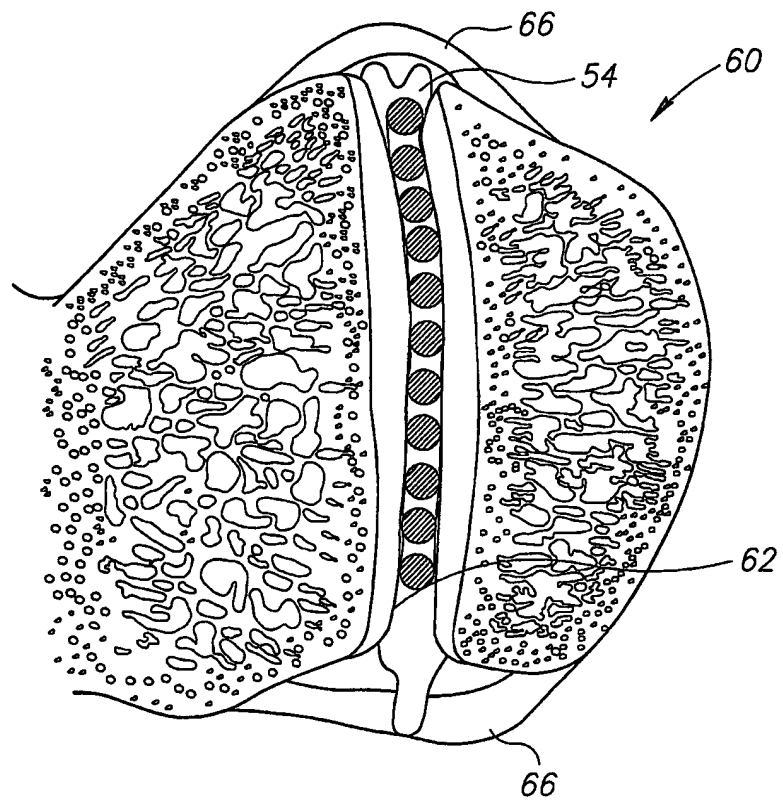


FIG. 6A

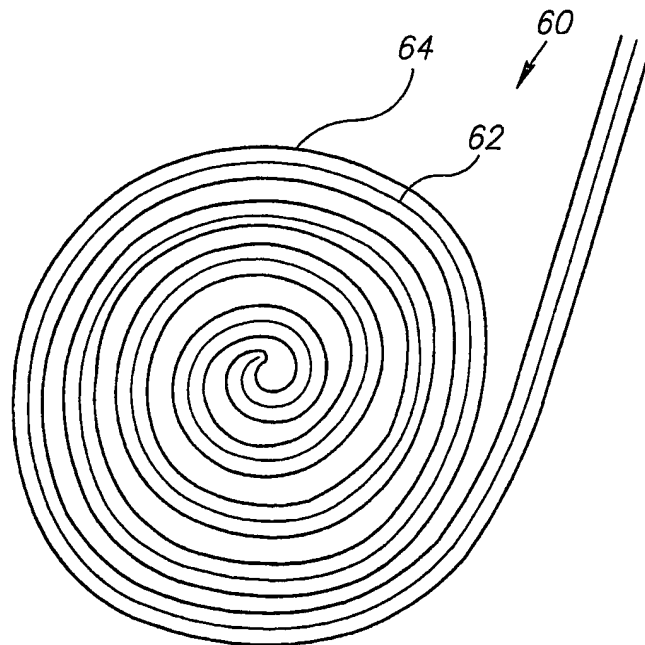


FIG. 6B

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FIG. 7A

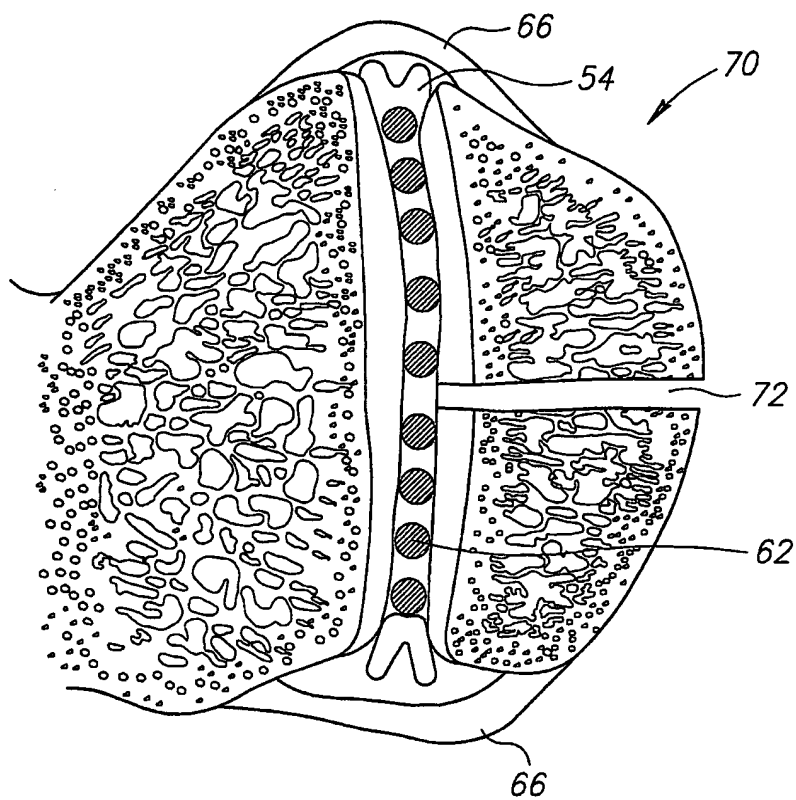
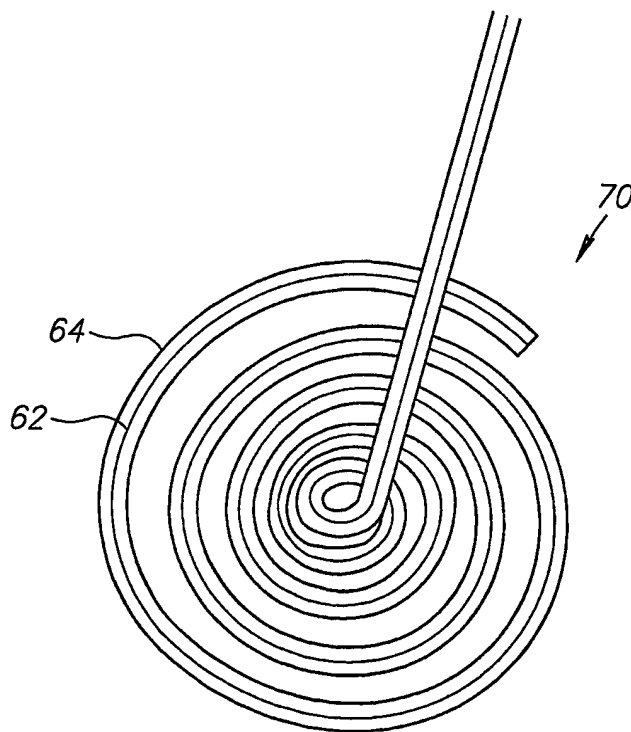


FIG. 7B



# INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/IL 03/01073

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/30248 A (REILEY MARK A) 3 May 2001 (2001-05-03) figures 2,4,5,12 page 13, line 18 - line 29 page 14, line 25 - line 30	1
A	-----	2
X	US 2003/004572 A1 (FALLIN T WADE ET AL) 2 January 2003 (2003-01-02) claims 1,8; figures 11,12,15,17 paragraphs [0098] - [0100], [0110]	1
X	US 5 571 191 A (FITZ WILLIAM R) 5 November 1996 (1996-11-05) claims 1,5; figures	1
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

### \* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"A" document member of the same patent family

Date of the actual completion of the international search

14 June 2004

Date of mailing of the international search report

23. 09. 2004

Name and mailing address of the ISA

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Authorized officer

Stach, R

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IL 03/01073

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-5

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.



FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5

An article comprising a facet prosthesis and an elastomeric cushioning element disposed in said facet prosthesis wherein said elastomeric cushioning element includes first and second mechanical fasteners at opposite ends thereof which are attachable to superior and inferior halves of the facet joint.

(problem: restricting the movement of the superior and inferior halves of the facet joint relativ to each other and to the facet prosthesis)

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2. claim: 6

An article comprising a facet prosthesis suitable for being at least partially mounted in a lumen artificially formed between superior and inferior halves of a facet joint and an elastomeric cushioning element disposed in said facet prosthesis wherein said elastomeric cushioning element includes a plurality of elastomeric balls disposed in said lumen and sealed in said lumen with end caps.

(problem: improving the mobility of the facet joint)

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3. claims: 7, 8

An article comprising a facet prosthesis suitable for being at least partially mounted in a lumen artificially formed between superior and inferior halves of a facet joint and an elastomeric cushioning element disposed in said facet prosthesis wherein said elastomeric cushioning element includes a wire coil coated with an elastomeric material disposed in said lumen and sealed in said lumen with end caps.

(problem: facillitating the implantation of a facet prosthesis)

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IL 03/01073

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0130248	A	03-05-2001	AU 776041 B2	26-08-2004
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Caution: TFAS™ is an investigational device in the United States. It is limited by Federal (United States) Law to investigational use.

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## Total Facet Arthroplasty System (TFAS™)

TFAS™ is an articulating joint prostheses intended to restore normal motion and provide stabilization of spinal segments in skeletally mature patients. It can be used as an adjunct to laminectomy, laminotomy, neural decompression and facetectomy, in lieu of fusion, for treatment of instabilities or deformities of the lumbar spine including:

- Degenerative disease of the facets;
- Degenerative disease of the facets with instability;
- Grade 1 degenerative spondylolisthesis with objective evidence of neurologic impairment;
- Central or lateral spinal stenosis.



The Total Facet Arthroplasty System™ (TFAS™) is a modular implantable device that is intended to replace the facets and excised elements of the posterior lumbar spine following facetectomy and neural decompressive procedures. Implanted via an open posterior surgical approach, TFAS™ is fixed within the pedicles and provides immediate alignment and stabilization of the spinal segment at a single spinal level, L3-L4 or L4-L5, while maintaining anatomical ranges of motion. TFAS™ is comprised of implantable grade metal components offered in a range of sizes to address the specific anatomical requirements of each patient. Implant component selection is made based upon pre-operative imaging measurements and intra-operative trialing. Pedicle fixation of TFAS™ components is accomplished via the use of polymethylmethacrylate (PMMA) cement. Archus Bone Cement, containing 30% barium sulphate, is the only cement validated for use as a component of the TFAS™ system. A specialized set of instruments facilitate implantation of the TFAS™ components.